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NOVARTIS PHARMACEUTICAL CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
ONE HEALTH PLAZA 101/2
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EXAMINER	
DIXON, ANNETTE FREDRICKA	
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANDREW CLARK, CARLOS SCHULER, and
STEVE PABOOJIAN

Appeal 2010-008081
Application 09/414,384
Technology Center 3700

Before LINDA E. HORNER, MICHAEL C. ASTORINO, and
JOHN W. MORRISON, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Andrew Clark et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 21-36. Claims 1-20 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

THE INVENTION

Appellants' claimed invention relates to a "device for pulmonary delivery of an active agent formulation for increased systemic bioavailability of the active agent via absorption in the deep lung." Spec. 1, ll. 6-8. "The bioavailability is increased by modulating the flow rate of the aerosolized active agent in a manner that is independent of patient instruction and flow rate monitoring." Spec. 1, ll. 8-10. The invention is based on the observation that when an active agent is delivered to a patient at an initially low inspiratory flow rate, the bioavailability of the active agent increases as compared to delivery of the active agent at a constant but higher inspiratory flow rate. Spec. 7, ll. 25-28. Claim 21, reproduced below, is representative of the subject matter on appeal.

> 21. A device for controlling the delivery of an aerosolized active agent to the lungs of a human patient, said device comprising
>
> a valve that provides a high flow resistance of at least 0.4 $(\text{cm } H_2O)^{1/2}$ / SLM in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a lower flow resistance,
>
> wherein the lower flow resistance allows for a higher flow rate through the device.

Independent claims 28 and 32 are also directed to a device comprising a valve that provides a higher flow resistance in the inhalation direction at the onset of the patient's inhalation and that subsequently opens during the inhalation to provide a lower flow resistance which corresponds to a higher flow rate.

THE REJECTIONS

Appellants seek review of the following rejections:

1. The Examiner rejected claims 21, 24, 28, 32, 34, and 36 under 35 U.S.C. § 102(b) as anticipated by Piper (US 5,479,920; iss. Jan. 2, 1996).
2. The Examiner rejected claims 22, 23, 26, 27, 30, 31, and 33 under 35 U.S.C. § 103(a) as unpatentable over Piper.
3. The Examiner rejected claims 25, 29, and 35 under 35 U.S.C. § 103(a) as unpatentable over Piper and Carris (US 4,227,522; iss. Oct. 14, 1980).

ISSUE

Appellants argue the Examiner erred in finding that Piper's flapper valve 24 provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation and subsequently opens during inhalation to provide a lower flow resistance. Ans. 3-4; App. Br. 5-7. An issue presented by this appeal is whether the Examiner has established by a preponderance of the evidence that Piper discloses a valve that provides a higher flow resistance in the inhalation direction at the onset of inhalation and a lower flow resistance during inhalation.

ANALYSIS

Piper discloses an inhalation device including a one-way inhalation valve 24. Col. 4, l. 22. Piper describes that valve 24 is a conventional flapper valve that opens to permit flow in one direction but closes to prevent flow in the other direction. Col. 4, ll. 23-25. Specifically, Piper discloses

that valve 24 permits ambient air to be drawn in during inhalation but closes during patient exhalation. Col. 4, ll. 25-28. Piper states:

> In this manner, when the patient exhales, inhalation valve **24** closes and pressure builds up within the breathing circuit to a level above atmospheric pressure due to the resistance across the exhalation circuitry in the breathing circuit. Similarly, when the patient inhales, valve **24** opens and pressure in the breathing circuit drops to a level below atmospheric pressure.

Col. 4, ll. 28-34.

Piper does not describe how the valve opens when the patient begins to inhale, the flow resistance of the valve in the inhalation direction at the onset of inhalation, or the flow rate through the valve during the remainder of the inhalation phase. Thus, the Examiner's finding that at the onset of inhalation the flow resistance of the Piper's valve would be high and as the user continues to inhale, the flow resistance would become lower appears to be based on speculation and conjecture. Ans. 3-4. Rejections under 35 U.S.C. § 102 cannot be based on speculation and conjecture. Therefore, it is our conclusion that the Examiner has not established by a preponderance of the evidence that the inhalation valve 24 of Piper provides a high flow resistance in the inhalation direction at the onset of the patient's inhalation and subsequently opens during the inhalation to provide a lower flow resistance. As such, we cannot sustain the Examiner's rejection of independent claims 21, 28, and 32, or their dependent claims 24, 34, and 36, under 35 U.S.C. § 102(b) as anticipated by Piper.

The Examiner relies on the same unsubstantiated finding in the rejections under 35 U.S.C. § 103(a) of claims 22, 23, 26, 27, 30, 31, and 33

based on Piper and of claims 25, 29, and 35 based on Piper and Carris. Ans. 7-9. Accordingly, for the same reason, we cannot sustain the rejections under 35 U.S.C. § 103.

CONCLUSION

The Examiner has not established by a preponderance of the evidence that Piper discloses a valve that provides a higher flow resistance in the inhalation direction at the onset of inhalation and a lower flow resistance during inhalation.

DECISION

The decision of the Examiner to reject claims 21-36 is REVERSED.

REVERSED

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